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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,190	10/29/2001	Karin Connors	EP01-002C	7347

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,190	CONNORS ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Jan 23, Aug 25,03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-12 are pending and are examined in the instant action.

Information Disclosure Statement

2. Applicant's IDS, forms 1449, filed 27 January 2003 and 25 August 2003, are acknowledged and signed copies included with the Office Action.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See ¶ 00100. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112-2nd

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 are rejected under 35 USC § 112-2 for the following reasons

In claims 1-12, "ANT1" is an abbreviation or an acronym. The full name should be spelled out at least once, preferably at the first recitation of the abbreviation. This should be followed by the abbreviation in parentheses; suggested language is: "Anthocyanin 1 (ANT1)".

In claim 2, hybridization under "high stringency conditions" is indefinite, since the conditions need to be specified.

Corrections or clarifications are required.

Claim Rejections - 35 USC § 112, first paragraph

Written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claims 1, 3, and 4 are drawn to an isolated polynucleotide comprising a nucleic acid sequence which encodes or is complementary to a sequence which encodes an ANT1 polypeptide having at least 70%, 80% or 90%, respectively, sequence identity to the amino acid sequence of SEQ ID NO: 2. However the specification does not disclose what structural features would be conserved in the claimed sequence that would result in the claimed activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.ed 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Claims 7-12, dependent on claim 1, have the same problem as claim 1, which is drawn to a polypeptide having at least 70% sequence identity.

Claim 2 is drawn to the polynucleotide of claim 1 comprising a nucleic acid sequence that hybridizes under high stringency conditions to the nucleic acid sequence of SEQ ID NO: 1 or the complement or a fragment thereof. The fragment length is unspecified, and may be as little as a single nucleotide . However the specification does not disclose what structural features would be conserved in the claimed sequence that would result in the claimed activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have recognized Applicants to have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111).

Claim Rejections - 35 USC § 112 Enablement

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising SEQ ID NO: 1 or a polynucleotide encoding amino acid sequence SEQ ID NO: 2, does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims: Claims 1, 3, and 4 are drawn to an isolated polynucleotide comprising a nucleic acid sequence which encodes or is complementary to a sequence which encodes an ANT1 polypeptide having at least 70%, 80% or 90%, respectively, sequence identity to the amino acid sequence of SEQ ID NO: 2. Claims 7-12, dependent on claim 1, are drawn to a plant transformation vector, a transgenic plant cell, a method of producing an ANT1 phenotype in a plant, a transgenic plant, a plant part, and a method of

selecting a transformed plant comprising a first polynucleotide comprising introducing into progenitor cells of the plant a plant transformation vector comprising the first polynucleotide and an ANT1 polynucleotide of claim 1, and growing the progenitor cells to produce a plant that displays the ANT1 phenotype, wherein the plant that displays the ANT1 phenotype is selected as a transformed plant comprising the first polynucleotide.

The state of the art is such that one skilled in the art cannot predict which nucleic acid which encodes or is complementary to a sequence which encodes an ANT1 polypeptide having at least 70% identity to the amino acid sequence of SEQ ID NO: 2. will encode a protein with the same activity as a protein of SEQ ID NO: 2. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspect of the protein, is extremely complex , and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie, et al, Science, Vol 247, pages 1306-1310, 1990, see especially page 1306). For example the replacement of a glycine residue located within the START domain of either the PHABULOSA of PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell, et al , Nature vol 411 (6838): pages 709-713, 2001, see especially page 710, left column 2nd ¶).

Isolating DNA fragments using stringent hybridization conditions (see claim 2), does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe or sequence of interest.

Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^{0}C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden

In view of the breadth of the claims (any nucleic acid sequence which encodes or is complementary to a sequence which encodes an ANT1 polypeptide having at least 70%, 80% or 90%, respectively, sequence identity to the amino acid sequence of SEQ ID NO: 2, any polynucleotide sequence polynucleotide of claim 1 comprising a nucleic acid sequence that hybridizes under high stringency conditions to the nucleic acid sequence of SEQ ID NO: 1 or the complement or a fragment thereof of any length) the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the

specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Remarks

10. No claims are allowed. SEQ ID NO: 1 and SEQ ID NO: 2 and sequence with at least 70% identity thereto, are free of the prior art of record. Claims 5 and 6, if rewritten as independent claims, are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
February 21, 2004

DAVID T. FOX
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GROUP ~~180~~ 1638